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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/053,053

01/16/2002

Lee L. Swanstrom

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21378

7590

09/26/2008

APPLIED MEDICAL RESOURCES CORPORATION

22872 Avenida Empresa

Rancho Santa Margarita, CA 92688

EXAMINER

ALIKHANI, SHADI

ART UNIT

PAPER NUMBER

3734

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/053,053	<b>Applicant(s)</b> SWANSTROM, LEE L.	
	<b>Examiner</b> SHADI ALIKHANI	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 4-9, 11, 20, 41 and 51-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 10, 12-19, 21-40, 42-50 and 60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Status of Claims*

1. This action is in reply to the application filed on 01/16/2002 and the amendment filed on 04/30/2008.
2. Claims 4-9, 11, 20, 41, and 51-59 were previously/currently have been canceled.
3. Claims 1, 2, 3, 10, and 40 have been amended.
4. Claim 60 has been added.
5. Claims 1-3, 10, 12-19, 21-40, 42-50, and 60 are currently pending and have been examined.

### *Claim Rejections - 35 USC § 103*

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 10, 12, and 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (6,350,278) in view of Mueller et al. (US 4,705,040).

#### **Claim 1:**

Lenker as shown discloses the following limitations:

- *means for transporting said implant into said hollow body organ* (Fig. 16-23);
- *a removable expansion assembly releasably engageable with said implant* (Fig. 23A-B, #340),
- *said removable expansion assembly includes a plurality of peripheral struts* (342),
- *said struts extending generally parallel to a longitudinal axis and spaced angularly thereabout* (Fig. 23B, #342),
- *said struts include like proximal ends and distal ends* (see Fig. 23A),

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- *said proximal ends being free of mechanical connection (Fig. 23B, #342);*
- *said distal ends being secured together and connected to a tube (348)*
- *and a cap (344), said cap being mounted on a central strut slidably (col. 3, ln 29-31) disposed within said tube*
- *wherein said cap is movable between a first position (Fig. 23A),*
- *wherein said proximal end are captured within said cap (see Fig. 23A, #344 and #342), and*
- *a second position, wherein said proximal ends are released from said cap (Fig. 23B);*
- *means for dilating said expansion assembly and expanding a portion of said implant against said vessel wall (Fig. 23B, #342);*
- *means for collapsing said expansion assembly and releasing (Fig. 23B, #344) said portion of said implant.*

Lenker discloses the limitations as shown above. Lenker does not explicitly disclose a *means for fastening said portion of said implant to said vessel wall of said organ while said expansion assembly holds said portion against said vessel wall*, but Mueller et al. in at least (Fig. 3a, #10) do.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lenker's implant apparatus to include Mueller's fastening means, because such a modification would secure the implant to the target wall.

**Claims 10 and 12:**

Lenker discloses the limitations as shown above and further discloses:

- *said means for dilating said expansion assembly includes means for translating said central strut distally (Fig. 23A-B) to urge said end cap (344) to impinge on said proximal ends of said peripheral struts while holding said peripheral struts stationary or urging them in a proximal direction (Fig. 23B, #350) to thereby compress said peripheral struts axially.*

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- *means for translating said peripheral struts distally along said longitudinal axis to move said proximal ends of said peripheral struts distally with respect to said means for fastening said portion of said implant to said vessel wall (Fig 23B Item 350)*

**Claims 31-36:**

Lenker discloses the limitations as shown above. Lenker does not explicitly disclose the following limitations, but Mueller as shown discloses the following fastening means:

- *said means for fastening includes a fastener member adapted to be inserted within the implant (Fig. 3a, #10).*
- *at least one flexible tie connector extending from the fastener member (Fig. 3, #12).*
- *further including needle means for containing said fastener member and flexible tie connector (Fig 3, #30), and*
- *means for driving said needle means through the exterior of said vessel wall to pierce said vessel wall and said implant (Fig 2, #52);*
- *said means for driving includes an endosurgical tool (Fig 2);*
- *push rod means for discharging said fastener member from said needle mean into the interior of said implant (Fig 2b, #54),*
- *said at least one flexible tie connector including an external portion extending from said fastener member exteriorly of said vessel wall (Fig 3);*
- *means for applying tensile force to said external portion of said at least one flexible tie connector, whereby said implant and said vessel wall are clamped together between said fastener member and said external portion of said at least one flexible tie connector (col. 2, ln 15).*
- Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Lenker's implant apparatus to include Mueller's fastening means. Such a modification would secure the implant to the target wall.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lenker's implant apparatus to include Mueller's fastening means, because such a modification would secure the implant to the target wall.

8. Claims 2, 15, and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (US 6,350,278) in view of Mueller et al. (US 4,705,040) as applied to claim 1 above, and further in view of Hughes et al. (US 4,728,328).

**Claims 2, 15, and 24-25:**

The combination of Lenker and Mueller disclose the limitations as shown above. The combination does not disclose the following limitations, but Hughes et al. as shown do:

- *said implant comprises a tubular, sleeve-like component free of mechanical structure (Fig 1).*
- *wherein said tubular, sleeve-like component includes at least one cuff (14) formed at a proximal end thereof;*
- *wherein said tubular, sleeve-like component includes at least one cuff (14) formed at one end thereof;*
- *wherein said at least one cuff includes an end portion (18) of said tubular, sleeve-like component folded retroflexively to impinge on the exterior of said component (Fig 1);*

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Lenker and Mueller's implant assembly to include Hughes' tubular sleeve. Such a modification would ensure long-term stability of the implant and reduce infection.

9. Claims 3 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (6,350,278) in view of Mueller et al. (US 4,705,040) and Hughes et al. (US 4,728,328) as applied to claims 2 and 15 above, and further in view of Cox et al. (US 2003/0023301).

**Claims 3 and 16-19:**

The combination of Lenker/Mueller/Hughes disclose the limitations as shown above. The combination does not disclose the following limitations, but Cox et al. as shown do:

- *said removable expansion assembly is disposed to translate concentrically within said tubular, sleeve-like component free of mechanical structure (Fig 1)*
- *a catheter assembly having a first tube (Fig 1, #20);*
- *said first tube includes a lumen (Fig 1, #20) adapted to receive said tubular, sleeve-like component, said first tube having a diameter dimensioned so that the proximal end of said first tube engages said cuff in end-abutting relationship;*
- *said tubular, sleeve-like component is disposed in said lumen in a radially contracted state (Fig 1);*
- *said catheter assembly includes a second tube disposed for axial translation concentrically within said first tube (Fig. 1, #11), said second tube having a proximal end dimensioned to engage the distal end of said tubular, sleeve-like component in end-abutting relationship.*

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Lenker, Mueller, and Hughes' implant assembly to include Cox's catheter and tubes. Such a modification would protect the vessel from abrasion by the expansion member and force the implant out of the sleeve. The limitations following the phrases "adapted to" and "dimensioned to" are considered to be functional language and thus require nothing more than the ability to so perform.

10. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (6,350,278) in view of Mueller et al. (US 4,705,040) as applied to claim 7 above, and further in view of Cox et al. (US 2003/0023301).

**Claims 13 and 14:**

The combination of Lenker and Mueller disclose the limitations as shown above. The combination does not disclose the following limitations, but Cox et al. as shown do:

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- *said removable expansion assembly includes a confinement tube (Fig. 1-3, #20), said confinement tube having a lumen dimensioned to receive said peripheral struts in a non-expanded, collapsed state (see Fig. 1-3; paragraph [0042]);*
- *said confinement tube is translatable with respect to said peripheral struts to move said confinement tube selectively into concentric confinement of said peripheral struts (paragraph [0042]).*

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Lenker and Mueller's expansion assembly to include Cox's tube assembly. Such a modification would protect the vessel from abrasion by the expansion member.

11. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (6,350,278) in view of Mueller et al. (US 4,705,040) and Hughes et al. (US 4,728,328) as applied to claim 2 above, and further in view of Trescony et al. (US 5,653,745).

**Claims 21 and 22:**

The combination of Lenker/Mueller/Hughes disclose the limitations as shown above. The combination does not disclose the following limitations, but Trescony et al. as shown do:

- *said tubular sleeve-like component (Fig. 1, #10) includes means for increased longitudinal stiffness (col. 3, ln 56-67);*
- *wherein said means for increased longitudinal stiffness includes a plurality of pleats (Fig. 1, #12) extending longitudinally in said tubular, sleeve-like component (Fig. 1).*

NOTE: Trescony teaches pleats extending longitudinally (Fig 1). Due to the substantially similar structure of the reference and the Applicant's implant, the Examiner considers the pleats to increase longitudinal stiffness.

Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Lenker, Mueller, and Hughes' implant assembly to include



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Trescony's pleats. Such a modification would provide longitudinal support reducing stretching making the implant more durable.

12. Claims 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (6,350,278) in view of Mueller et al. (US 4,705,040) and Hughes et al. (US 4,728,328) as applied to claim 2 above, and further in view of Imbert et al. (US 5,607,466).

**Claims 21 and 23:**

The combination of LenkerMueller/Hughes disclose the limitations as shown above. The combination does not disclose the following limitations, but Imbert et al. as shown do:

- *said tubular sleeve-like component (Fig. 2, #2) includes means for increased longitudinal stiffness (col. 6, ln 53-59);*
- *wherein said means for increased longitudinal stiffness includes a plurality of stiffener struts (col. 6, ln 53-59) secured longitudinally in said tubular, sleeve-like component.*

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Lenker, Mueller, and Hughes' implant assembly to include Imbert's strut, because it is better "...held together on its own and does not twist when released, so the stent can be removed again reliably from the vessel with no problem after a temporary period of use." (Imbert et al., col. 4, ln 18-21).

13. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (6,350,278) in view of Mueller et al. (US 4,705,040) and Hughes et al. (US 4,728,328) as applied to claim 2 above, and further in view of Chevillon et al. (US 6,248,116).

**Claims 26-27:**

The combination of LenkerMueller/Hughes disclose the limitations as shown above. The combination does not disclose the following limitations, but Chevillon et al. as shown do:

- *further including at least one reinforcing band (Fig. 1, #140a) incorporated in said at least one cuff;*

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- *said at least one reinforcing band is resiliently (col. 7, ln 1-3) biased to expand radially outwardly (Fig. 1, #140a).*

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Lenker, Mueller, and Hughes' implant assembly to include Chevillon's bands. Such a modification would reinforce the implant against the vessel wall.

14. Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (6,350,278) in view of Mueller et al. (US 4,705,040) and Hughes et al. (US 4,728,328) as applied to claim 2 above, and further in view of White et al. (US 2006/0015176).

**Claims 28-30:**

The combination of LenkerMueller/Hughes disclose the limitations as shown above. The combination does not disclose the following limitations, but White et al. as shown do:

- *said implant has a Y-configuration (Fig 9);*
- *wherein one branching end of said Y-configuration comprises an elongated tubular leg (Fig. 9, #28);*
- *wherein one branching end of said Y-configuration comprises a short connector leg (Fig 9, #29).*

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify White's Y-configuration. Such a modification would be used for placement in a bifurcated blood vessel.

15. Claims 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (6,350,278) in view of Mueller et al. (US 4,705,040) as applied to claim 1 above, and further in view of Haber et al. (US 5,201,743).

**Claims 37-39:**

The combination of LenkerMueller disclose the limitations as shown above. The combination does not disclose the following limitations, but Haber et al. as shown do:

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- *said means for applying tensile force include means for winding said at least one flexible tie connector about a winding axis (Fig. 6, #118).*
- *said means for winding including a torque-limiting mechanism (Fig. 6; col. 4, ln 8-20)*
- *said means for winding includes an endosurgical tool (Fig 6).*

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Lenker and Mueller's implant assembly to include Haber's means for winding. Such a modification would secure the fastener to the tissue.

16. Claims 40 and 42-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (6,350,278) in view of Cox et al. (US 2003/0023301).

**Claim 40:**

Lenker et al. disclose the limitations as shown above and further disclose:

- *a plurality of peripheral struts (Fig. 23B, #342),*
- *said struts having a relaxed state in which said peripheral struts extend generally parallel to a longitudinal axis and are spaced angularly thereabout (Fig. 23B, #342),*
- *said peripheral struts include proximal ends, said proximal ends being free of mechanical connection (Fig 23B);*
- *means for urging (350) said peripheral struts to a bowed state; Lenker et al. disclose urging mechanism (350) that is capable of urging the struts into a bowed state when pulled back against the struts (342); wherein*
- *said peripheral struts (342) expand radially outwardly from said longitudinal axis, to thereby dilate said surgical implant (Fig. 23B, element P).*

Lenker et al. do not disclose the following limitations, but Cox et al. as shown in at least paragraph [0042] disclose *said plurality of peripheral struts being removably disposed within said surgical implant*. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Lenker's expansion assembly to include Cox's removable

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struts, because it can "...ensure that stent stays in place...during delivery to the desired arterial location." (Cox et al., paragraph [0042])

**Claims 42-48:**

Lenker et al. disclose the limitations as shown above and further disclose:

- said peripheral struts include like distal ends, said distal ends being secured together (Fig 23A).
- *said means for urging said peripheral struts includes means for compressing said peripheral struts along said longitudinal axis to effect bowing of said peripheral struts radially outwardly from said longitudinal axis* (Fig. 23B). Note that Lenker et al. disclose urging mechanism (350) that is capable of urging the struts into a bowed state when pulled back against the struts (342);
- *said means for compressing includes an end cap (344), said end cap including means for releasably impinging on said proximal ends of said peripheral struts* (Fig 23A-B).
- *a central strut* (see Fig. 23A-B) *extending parallel to said peripheral struts, said central strut being secured to said end cap* (Fig. 23B, #344 and #350).
- *means for translating said central strut distally to urge said end cap to impinge on said proximal ends of said peripheral struts and compress said peripheral struts axially* (Fig 23B).
- *said means for releasably impinging includes a recess formed in a distal surface of said end cap* (Fig 23A).
- *means for translating said peripheral struts distally* (Fig. 23A-B) *along said longitudinal axis to move said proximal ends of said peripheral struts distally with respect to said end cap* (see Fig. 23A-B).

**Claims 49-50:**

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Lenker et al. do not disclose the following limitations, but Cox et al. as shown do:

- *a confinement tube (Fig. 1-3, #20), said confinement tube having a lumen dimensioned to receive said peripheral struts in a non-expanded, radially-collapsed state (see Fig. 1-3; paragraph [0042]);*
- *said confinement tube is translatable with respect to said peripheral struts to move said confinement tube selectively into concentric confinement of said peripheral struts (paragraph [0042]).*

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Lenker's expansion assembly to include Cox's tube assembly. Such a modification would protect the vessel from abrasion by the expansion member.

The Examiner notes that although the Lenker reference discloses the implant within the expansion member, it is common in the art as shown by the Cox reference to dispose the implant on the exterior of the expansion member. Because the Lenker assembly is fully capable of expanding an implant, the Examiner considers the Cox reference to teach how this would be achieved.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHADI ALIKHANI whose telephone number is (571)270-5305. The examiner can normally be reached on Monday - Thursday 10AM - 4PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/  
Primary Examiner, Art Unit 3734  
/Shadi Alikhani/  
Examiner, Art Unit 3734

09/18/2008